UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Total Toxicology Labs, LLC,

Plaintiff,

v. Civil Case No. 19-12000

Alex M. Azar, II. Secretary of the United States Department Of Health and Human Services, *et al.*,

Sean F. Cox
United States District Court Judge

Defendants.
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OPINION & ORDER
DENYING PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

The plaintiff in this case, Total Toxicology Labs, LLC d/b/a TT Labs, LLC ("TT Labs"), provides clinical laboratory services to patients nationwide and is a participant in the Medicare Payment Process within the Medicare reimbursement system. As a participant in that system, TT Labs is subject to audits of its billings. In 2017, TT Labs learned that government auditors found that it had overcharged for services provided to Medicare beneficiaries. TT Labs challenged the auditors' decisions at two levels of the Medicare administrative appeals process but, after those appeals, TT Labs was still found to have been overpaid for its services. TT Labs pursued an appeal at the third level of review, but has not yet been given a hearing date because the system is backlogged such that instead of receiving a hearing in 90 days, it could take three years or more for that administrative appeal to take place. Meanwhile, the Government has begun to start recouping the money that the audits showed were overpaid to TT Labs, as the regulatory scheme allows. The government recovers the amount due from the money that it

would otherwise pay for new reimbursement claims until the service provider's debt is paid in full.

The Government contends that TT Labs currently owes it a significant balance for overpayments, that it intends to recoup going forward. Not wanting to wait three years for the third-level administrative appeal, and not having sought a hardship exception or pursuing other options under the regulatory scheme, such as escalation procedures, TT Labs filed this action asserting a due process claim and seeking a preliminary injunction. It asks this Court to enjoin the Government from any further recoupment until such time as it gets a third-level administrative appeal heard and decided.

At an early status conference, counsel advised the Court that a federal district court in Tennessee had issued a preliminary injunction in a similar case with another Medicare service provider, A1 Diabetes, and that a decision on the appeal in that case would likely decide several of the issues in play here. The United States Court of Appeals for the Sixth Circuit, however, did not rule on the issues and, instead, issued a decision wherein it identified a host of questions and concerns that need to be addressed before a decision on an preliminary injunction in this kind of case could be made. Thus, the Sixth Circuit vacated the district court's preliminary injunction and remanded so that the parties and district court could address the various issues and questions it identified.

The motion in this case has been fully briefed and TT Labs has not requested an evidentiary hearing. This Court heard oral argument on December 17, 2019. As explained below, TT Labs has not answered all of the various questions raised in *A1 Diabetes* as to the factors to be considered relating to the likelihood of success on the merits of its due process

claim. And, even if it had, *and* the answers weighed in its favor such that it established a substantial likelihood of success on the merits of its due process claim, then this Court would still have to evaluate the other preliminary injunction factors. That includes the critical factor of the risk of irreparable harm to the plaintiff absent the requested injunctive relief. Although TT Labs has a theoretically plausible claim of serious financial injury absent the requested injunction, it has failed to make the requisite evidentiary showing of certain and immediate irreparable financial harm needed to obtain a preliminary injunction. As such, the Court shall DENY the motion.

BACKGROUND

Plaintiff TT Labs filed this action against Defendant Alex M. Azar, II, Secretary of the United States Department of Health and Human Services and Seema Verma, Administrator for the Centers for Medicare and Medicaid Services ("the Government") asserting the following three counts: 1) "Denial Of Procedural Due Process" (Count I); 2) "Ultra Vires" (Count II); and 3) "Violation Of The Administrative Procedures Act" (Count III). TT Labs's complaint alleges that the Government's "recoupment of the alleged overpayment has already caused Plaintiff devastating financial harm its continuance will cause continued financial harm, and possibly force Plaintiff out of business well before any ALJ could hear and decide the case pursuant to statutory administrative review. Without the temporary relief requested herein, Plaintiff is likely to suffer the fatal consequence of permanent closure." (Compl. at ¶ 41).

Pending before the Court is a motion filed by TT Labs seeking a preliminary injunction. TT Labs asks this Court to enjoin the Government "from any further recoupment or collection of alleged Medicare overpayments, including referral to the U.S. Treasury Department for

collection, until such time as an administrative law judge assigned to the Office of Medicare Hearings and Appeals ('OMHA') hears Plaintiff's pending appeal and renders a decision thereon." (ECF No. 3 at PageID.156).

TT Labs's motion does not request an evidentiary hearing. Rather, TT Labs states that its "Motion is based on the *facts sworn in the Verified Complaint* filed in this action and the exhibits attached thereto, and the Brief in Support filed herewith, and applicable law." (ECF No. 3 at PageID.156) (emphasis added). There are no declarations or affidavits attached as exhibits to the motion.

TT Labs's complaint is titled, "*Verified* Complaint For Temporary Restraining Order And Preliminary Injunction." (ECF No. 1) (emphasis added). A verified complaint has the same force and effect as a signed and notarized affidavit. *Williams v. Browman*, 981 F.2d 901, 905 (6th Cir. 1992). Its title notwithstanding, TT Labs's complaint was neither accompanied by a sworn statement nor attested to under oath, and thus it is *not* a verified complaint. *See El Bey v. Roop*, 530 F.3d 407, 414 (6th Cir. 2008) (noting that a "verified complaint" is one that is signed under the penalty of perjury pursuant to 28 U.S.C. § 1746); *see also Williams*, *supra*; 28 U.S.C. § 1746.

TT Labs has not submitted any affidavits or declarations in support of its motion, such as an affidavit attesting to its financial condition or the impact of the recoupment on same.

Soon after this case was filed, this Court held a status conference with counsel. Counsel advised the Court that a district court in Tennessee had granted a preliminary injunction in a

similar case against the Government, without holding an evidentiary hearing[1], and in favor of another Medicare service provider, A1 Diabetes & Medical Supply. They further advised that an appeal before the Sixth Circuit in that case would very likely answer many of the same issues in this case, such as whether subject matter jurisdiction exists, whether a Medicare service provider has a protected interest for purposes of a due process claim, and whether the issuance of a preliminary injunction is appropriate. The parties agreed to a briefing schedule as to the motion in this case.

The Government filed a brief in opposition to the preliminary injunction motion. It argues that TT Labs is unlikely to succeed on the merits of its due process claim because, among other things, TT Labs has not asserted a protected property interest for purposes of a due process claim, and available procedures amply protect against the risk of an erroneous deprivation here.

The Government further argues that TT Labs has not shown it is likely to suffer irreparable harm in the absence of a preliminary injunction and noted that TT Labs had not presented *any evidence* as to its alleged financial harm:

> A showing of probable irreparable harm is the single most important prerequisite for the issuance of a preliminary injunction. *Lucero v. Detroit Pub. Schs.*, 160 F.Supp.2d 767, 901 (E.D. Mich. 2001). Without such a showing, the Court simply cannot issue a preliminary injunction. *Id*. Thus, in this matter, the Court need not assess whether Plaintiff's financial condition is as bad as alleged, or whether the entity's financial condition is sufficient proof of irreparable harm, because Plaintiff has failed to set forth any evidence to support its claim of financial hardship. Because Plaintiff offered no evidence, this critical element has not been met, and the motion must be denied. *DPLSA* at *10 (DPLSA has not provided any evidence, besides mere speculation, that any arbitration award or MERC award in its favor would be so great as to force the City of Detroit into

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[1]*See A1 Diabetes & Med. Supply v. Azar,* 2018 WL 7283329 at * 1-3 (W.D. Mich. 2018) (noting that the Plaintiff Medicare service provider had filed a "verified complaint" and that the Court ruled following hearing oral argument, not an evidentiary hearing.)

great financial hardship).

(ECF No. 10 at PageID.280).

On August 22, 2019, the Sixth Circuit issued a published opinion in *A1 Diabetes*, vacating the district court's preliminary injunction and remanding for proceedings consistent with the opinion. *A1 Diabetes & Med. Supply v. Azar*, 937 F.3d 613 (6th Cir. 2019). In it, the appellate court vacated the preliminary injunction issued by the district court, and spelled out a number of issues that were unclear and required answers.

On September 6, 2019 – and with the benefit of the Sixth Circuit's published opinion in *A1 Diabetes* – TT Labs filed a Reply Brief in support of its motion. Mindful that the Sixth Circuit has issued its decision in *A1 Diabetes* prior to the filing of it, this Court granted TT Labs's request to exceed the page limitation under the local rule and allowed it to file a reply brief of 18 pages. A good portion of it is devoted to the issue of whether TT Labs has a protected property interest, something the Sixth Circuit assumed without deciding in *A1 Diabetes*. TT Labs's reply brief does not identify any evidence to substantiate its allegations regarding its alleged financial injuries, nor does it address various questions posed by the Sixth Circuit in *A1 Diabetes*.

ANALYSIS

"A preliminary injunction is an extraordinary measure that has been characterized as 'one of the most drastic tools in the arsenal of judicial remedies.'" *Bonnell v. Lorenzo*, 241 F.3d 800, 808 (6th Cir. 2001) (citation omitted).

In reviewing a request for a preliminary judgment, a district court looks at four factors: 1) the plaintiff's likelihood of success on the merits; 2) the risk of irreparable harm to plaintiffs

absent injunctive relief; 3) the risk of harm to others resulting from an injunction; and 4) the broader public interest. *A1 Diabetes*, 937 F.3d at 618 (citing *Mich. State AFL-CIO v. Schuette*, 847 F.3d 800, 803 (6th Cir. 2017)).

The movant bears the burden of demonstrating its entitlement to the preliminary injunction sought, and its burden is a heavy one. A preliminary injunction is an extraordinary remedy which should be granted only if the movant carries his or her burden of proving that the circumstances clearly demand it. *Leary v. Daeschner*, 228 F.3d 729, 739 (6th Cir. 2000).

In *A1 Diabetes*, the Sixth Circuit reviewed a district court's grant of a preliminary injunction to a Medicare service provider who, like TT Labs, was facing recoupment while awaiting a third-level administrative review. In doing so, it did not proceed past the first factor (the plaintiff's likelihood of success on the merits), finding that "more information" was needed before such an injunction could be sustained.

I. Likelihood Of Success On The Merits

Like the plaintiff in *A1 Diabetes*, TT Labs asserts that it has a substantial likelihood of success on the merits of its procedural due process claim. As to that claim:

> The Fifth Amendment prohibits the federal government from depriving any person "of life, liberty, or property, without due process of law." U.S. Const. amend. V. To prevail on such a claim, [the plaintiff, here TT Labs,] must show that the government deprived it of a "liberty or property" interest and did so without the kind of "process" the Constitution requires.

Id. at 618-19.

In *A1 Diabetes*, the Sixth Circuit recognized that various courts have disagreed about whether a Medicare service provider has a property interest in getting paid for what it provides. It declined to resolve that question and, instead, assumed without deciding that A1 had such a

property interest. *Id*. at 619.

It then proceeded to consider what process would be owed, under *Matthews v. Eldridge*, 424 U.S. 319 (1976):

> *Matthews v. Eldridge*, once again, enters the picture. It tells us to balance four factors in deciding what process [a Medicare service provider like] A1 deserves: "[1] the private interest that will be affected by the official action; . . . [2] the risk of an erroneous deprivation[;] . . . [3] the probable value, if any, of additional or substitute procedural safeguards; and . . . [4] the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail." 424 U.S. at 335, 96 S.Ct. 893.

Id. at 619.

The Sixth Circuit found that the first and fourth factors were "relatively straightforward" to apply.

A. The First Factor - The Private Interest That Will Be Affected By The Official Action

Notably, the plaintiff company in *A1 Diabetes* receives nearly all of its revenue – 90% – from Medicare reimbursements. *A1 Diabetes & Med. Supply v. Azar*, 2018 WL 7283329 at * 1 (W.D. Tenn. 2018); *A1 Diabetes*, 937 F.3d at 616.

The Sixth Circuit found that the first factor weighed in favor of that Medicare service provider, explaining:

> As to the first one, A1 plainly has a significant "private interest": payment for services rendered. It's difficult for a company to stay in business without fresh revenue. As this case comes to us, the company already has laid off 25 people. And nearly 50 others will lose their jobs if A1 enters bankruptcy—which A1 claims is inevitable if the government may deduct all new reimbursement payments against the $7 million in recoupment payments now due. The future viability of a company—not to mention (though just mentioned) the jobs it sustains—hinges on whether it gets new reimbursements for new services provided. It's true that *this money* may look less important than other money subject to claims like this one—whether successful claims, *see Goldberg v. Kelly*, 397 U.S. 254, 264, 90 S.Ct. 1011, 25 L.Ed.2d 287 (1970) (identifying government

> welfare benefits as "the very means by which to live"), or unsuccessful claims, *see Mathews*, 424 U.S. at 340, 96 S.Ct. 893 (recognizing that the private interest in disability benefits is not so significant that a pre-termination hearing is necessary). But we must look at A1's "private interest" in part through its eyes, not exclusively through others' eyes. And there is plenty to appreciate from A1's vantage point.

Id. at 619.

The amount of the recoupment at issue here is substantially less than the seven million dollars at issue in *A1 Diabetes*. If this Court is reading TT Labs's Reply Brief correctly, the Government contends that TT Labs currently owes it a balance of approximately $800,000.00 for overpayments, that it wishes to recoup going forward. Moreover, this Court does not know what percentage of TT Labs's total revenue comes from Medicare reimbursements. Nevertheless, for purposes of this first factor of determining what process is owed, this factor weighs in favor of TT Labs, as the *A1 Diabetes* court instructed to look at the Medicare service provider's private interest, in part through its own eyes.

B. The Fourth Factor – The Government's Interest

The *Al Diabetes* Court found that the fourth factor, the government's interest, weighed in favor of the Government explaining:

> The fourth factor, by contrast, cuts in favor of the government. It seeks to recover on a timely basis millions of dollars that several government auditors agree it is owed and that two independent layers of administrative review confirm it is owed. This agency, like every federal agency, has ample reason to ensure that it does not waste the people's money. Just as the people's resources are finite, so are the government's. Delayed recoupment of over-billing puts Medicate at risk, and other government programs too.

Id.

In this case, this fourth factor weighs in favor of the Government for these same reasons.

C. The Second And Third Factors – The Risk Of Erroneous Deprivation And The Probable Value, If Any, Of Additional Or Substitute Procedural Safeguards

The second factor is the risk of an erroneous deprivation and the third factor is the probable value, if any, of additional or substitute procedural safeguards. As to those factors, in *A1 Diabetes*, the Sixth Circuit concluded that both of those "considerations remain clouded by a few questions and the need for a few more answers. Even after the district court's thoughtful decision, admirable appellate briefing, and helpful oral arguments in our court, some details about the administrative scheme and A1's choices under it remain unclear." *Id*. at 619-20.

The Sixth Circuit was hesitant to affirm the district court's grant of a preliminary injunction "in this setting" (ie., an injunction sought by a Medicare service provider facing recoupment while waiting for a third-level review) stating "[i]n view of the centrality of the likelihood-of-success factor to this appeal, and in view of the significance of giving a green light to federal due process claims in this setting, we think it prudent to obtain more information before resolving the point." *Id*. at 620.

The rest of the decision then spells out a host of unanswered questions and concerns that prevented the Sixth Circuit from determining whether the second and third factors weighed in favor of, or against, the issuance of a preliminary injunction:

> The record, for one, remains unclear about A1's choice not to take advantage of the escalation option. By statute, if an ALJ does not provide A1 its hearing and decision in ninety days, A1 may escalate its claim to the fourth and final level of administrative review—and then to district court review if the same problem raises its head. 42 U.S.C. § 1395ff(d)(3)(A)–(B). A1 submitted a timely appeal for an ALJ hearing on August 15, 2018. That started the ninety-day clock. If A1 had submitted a request for escalated review after that period ran, and if it had the same problem at the fourth level of review, it could have made it to district court

as early as February 2019. At that point, A1 could have asked for an injunction (on the merits of the recoupment claim rather than on the due process claim) to bar further recoupment while it litigated the auditors' decisions that underlie its claim before this court. At oral argument, A1 represented that it could stave off bankruptcy for ninety days, while waiting for an ALJ decision, but not three to five years. Why was the same not true for the six months it would take to escalate? And how exactly does escalation compromise, as opposed to avoid, due process problems?

Escalation, it's true, requires a party to forgo the right to a live hearing at the third level of the process. Absent the ALJ hearing, it's also true, the district court will be limited to the written administrative record, leaving A1 without the chance to cross-examine the government's statisticians. But these answers, too, leave questions. The Medicare Act generally requires that a provider who challenges an auditor's decision to submit *all* evidence in its favor before it reaches the third layer of review. *See* 42 U.S.C. § 1395ff(b)(3) ("A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the [second level of review] unless there is good cause which precluded the introduction of such evidence ...."). And the first and second levels of administrative review require the decisionmakers to provide detailed, written explanations for their decisions. 42 U.S.C. §§ 1395ff(b)(3), (c)(3)(E). By the third level of review, then, the provider and the government must have submitted all of their supporting evidence, and the decisionmakers must have explained any decision to reject a provider's claim. As for A1's desire to cross-examine the government's auditors, that right is qualified. Although the regulations allow agency officials and the contracted auditors who conducted the extrapolation to participate in the ALJ proceedings, 42 C.F.R. § 405.1010(a)(1), the regulations prohibit ALJs from subpoenaing agency officials to participate in a hearing. *Id.* § 405.1010(a) (2). Cross-examination, in other words, is not guaranteed, even at the ALJ hearings, which apparently often are decided by telephone and essentially on the written record. The parties also dispute the extent to which physician testimony on the medical necessity of charges is available at the ALJ hearing. Appellee's Br. 31; Reply Br. 12. What, then, exactly is provided in terms of additional fairness at the ALJ hearing? And relatedly what exactly would A1 give up by not seeking immediate recourse in federal court through escalation?

That leaves the other key question. The parties do not seem to have been aware of a recoupment option that might have allowed A1 to obtain an ALJ hearing before making most or even all of its recoupment payments. Nothing in the statute or regulations seems to prohibit the government from creating an installment-based repayment plan that accounts for a provider's financial distress *and* the government's log jam in resolving appeals at the third and fourth levels of review. For example: It is not clear when or whether the government must demand recoupment—either as a matter of statutory or regulatory authority. (How do we know, to be specific, that the Federal Claims Collection Act applies to Medicare-

> based claims? The relevant statute, 31 U.S.C. § 3711, does not seem to say.) It is not clear what kind of discretion and how much discretion the government has on timing. *See, e.g.*, 42 C.F.R. § 401.607(c)(3); *see also* 42 U.S.C. § 1395ddd(f)(1)(A); 42 C.F.R. § 405.379(h)(2). And it is not clear whether, if the government is statutorily obligated to collect recoupment and if it must do so within a certain time, it may delay the bulk of the recoupment payments until after the ALJ hearing and decision, keeping in mind that the delays stem from bureaucratic snags in *the government's* appeal process.
>
> Finally, we have unanswered questions regarding the statistics concerning the relief likely to be obtained at the third level of administrative review. In particular, how often does an entity obtain substantial relief at level three over any relief that it obtained at level two? And how should we account for the high rate of dismissals at level three?

Id. at 619-20 (italics in original). Because the record left those questions unanswered, the Sixth Circuit vacated the district court's order granting the Medicare service provider a preliminary injunction:

> To the end of answering these questions, we vacate the district court's order granting A1 a preliminary injunction and remand the case to the district court. On remand, the court is free to maintain the status quo by reissuing a temporary restraining order and other preliminary relief while the parties respond promptly to these (and any other relevant) questions. After obtaining this information, the district court remains free to reach the same or a different conclusion—and to explain how this new information either does or does not alter its initial conclusion. Once the parties and the court promptly complete that process, the losing party may appeal the district court's order on an expedited basis to this panel. At that point, we will decide whether additional briefing and oral argument are necessary.

Id. at 621.

The list of issues and questions raised by the Sixth Circuit in *A1 Diabetes* have not been answered by TT Labs, the party seeking the extraordinary relief of a preliminary injunction in this case.

Moreover, the Government's brief adds what appear to be *additional* issues that the *A1*

Diabetes court would want addressed. The Government states that "[a]lso potentially available to a provider who is subject to the ALJ backlog is the OMHA Settlement Conference Facilitation Program (SCF), which is an alternative dispute resolution option that mediates the dispute, (Exhibit A, Griswold Affidavit at ¶ 11), and the OMHA Statistical Sampling Initiative (SSI), which uses a statistical sampling to adjudicate a subset of an appellant's pending appeals and extrapolate the results to the universe of their pending appeals, resulting in a faster adjudication time. (*Id*.). Plaintiff has not submitted a request to participate in either the SCF or the SSI. (*Id*. at ¶ 13)." (ECF No. 10 at PageID.267).

II. The Risk Of Irreparable Harm To TT Labs Absent Injunctive Relief

Even if TT Labs had answered all of the various questions posed by the Sixth Circuit's decision in *A1 Diabetes* (which it has not), *and* the answers weighed in its favor such that it established a substantial likelihood of success on the merits of its due process claim, then this Court would still have to evaluate the other preliminary injunction factors.

That includes the risk of irreparable harm to the plaintiff absent the requested injunctive relief. As explained in *Contech Casting, LLC,* that is a critical factor:

> While no one factor is dispositive in deciding a motion for injunctive relief, courts have historically assigned great weight to the strength of the irreparable-injury showing. *See* 11A Charles Alan Wright, Arthur R. Miller, Mary Kay Kane, Richard L. Marcus, Federal Practice & Procedure § 2948.1, p. 139 (2d ed. 1995) ("Perhaps the single most important prerequisite for the issuance of a preliminary injunction is a demonstration that if it is not granted the applicant is likely to suffer irreparable harm before a decision on the merits can be rendered ..."). The Sixth Circuit agrees that it is "typically regarded as the most important" factor. *Lexington–Fayette Urban Cnty. Gov't v. BellSouth Telecomms., Inc.,* 14 Fed.Appx. 636, 639 (6th Cir. 2001). Its elevated status in the hierarchy of equitable considerations is reflected in the number of cases holding that injunctive relief should not be awarded in its absence. *See City of Los Angeles v. Lyons,* 461 U.S. 95, 111, 103 S.Ct. 1660, 75 L.Ed.2d 675 (1983) (injunction "unavailable absent a showing of irreparable injury"); *Patio Enclosures, Inc. v. Herbst*, 39

> Fed.Appx. 964, 967 (6th Cir. 2002) ("[T]he demonstration of some irreparable injury is a *sine qua non* for issuance of an injunction."); *Friendship Materials, Inc. v. Mich. Brick, Inc.*, 679 F.2d 100, 103 (6th Cir. 1982) ("Despite the overall flexibility of the test for preliminary injunctive relief, and the discretion vested in the district court, equity has traditionally required such irreparable harm before an interlocutory injunction may be issued.").

Contech Casting, LLC v. ZF Steering Sys., LLC, 931 F.Supp.2d 809, 823 (E.D. Mich. 2013). As further explained in that case:

> Regarding the second element of the *Overstreet* framework—irreparable harm—the law is settled that a party moving for a preliminary injunction must establish more than mere monetary injury. *See, e.g., Sampson v. Murray*, 415 U.S. 61, 90, 94 S.Ct. 937, 39 L.Ed.2d 166 (1974) ("[I]t seems clear that the temporary loss of income, ultimately to be recovered, does not usually constitute irreparable injury."); *Virginia Petroleum Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921, 925 (D.C.Cir.1958) ("[I]njuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough. The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, weighs heavily against a claim of irreparable harm.").
>
> At the same time, courts have recognized that the irreparable harm element of the preliminary injunction framework may be satisfied on a showing that, absent an injunction, financial hardship would be so severe that it would cause the moving entity to be "completely wiped out," thereby rendering "a later judgment on the merits meaningless." *Stenberg v. Cheker Oil Co.*, 573 F.2d 921, 924 (6th Cir. 1978). *See also Performance Unlimited, Inc. v. Questar Publishers, Inc.*, 52 F.3d 1373, 1382 (6th Cir. 1995) ("The impending loss or financial ruin of [a] business constitutes irreparable injury.").
>
> However, the moving party must show that irreparable harm is "both certain and immediate, rather than speculative or theoretical." *Mich. Coal. of Radioactive Material Users, Inc. v. Griepentrog*, 945 F.2d 150, 154 (6th Cir. 1991). *See also Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22, 129 S.Ct. 365, 172 L.Ed.2d 249 (2008) ("Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.").

Id. at 817-18.

Here, TT Labs has not made the requisite showing. TT Labs's complaint alleges, in a

conclusory fashion, that it will experience financial harm if the requested injunction is not issued. It alleges that it may "possibly" be forced out of business before it receives the third-level administrative decision it seeks. (Compl. at 9). Contrary to its title, the complaint is not a verified complaint, as explained *supra*. In addition, TT Labs has not requested an evidentiary hearing or submitted any declarations or affidavits to establish facts that would support its conclusory allegations regarding possible financial harm.

In *A1 Diabetes*, the plaintiff presented the district court with an *actual verified complaint*, and it included specific sworn factual statements to support its alleged financial harm absent the injunction. For example, the plaintiff established that it receives *nearly all* of its revenue – 90% – from Medicare reimbursements, in addition to being under already existing financial pressure due to declining reimbursement rates and razor thin profit margins. *A1 Diabetes & Med. Supply v. Azar*, 2018 WL 7283329 at * 1 (W.D. Tenn. 2018); (*see also* Verified Complaint in that case). The plaintiff company in *A1 Diabetes* included the sworn factual statement that it "will initiate bankruptcy proceedings" "[o]nce CMS initiates recoupment." *Id*. It also showed that it had already been required to lay off twenty five of its employees. *A1 Diabetes & Med. Supply v. Azar*, 937 F.3d at 619.

Here, all TT Labs has offered are unsupported, conclusory allegations. Thus, while TT Labs may have a theoretically plausible claim of irreparable financial injury, it has failed to make the requisite showing needed to obtain the extraordinary remedy of a preliminary injunction.

CONCLUSION & ORDER

For the reasons set forth above, IT IS ORDERED that Plaintiff's Motion for Preliminary Injunction is DENIED.

IT IS SO ORDERED.

s/Sean F. Cox
Sean F. Cox
United States District Judge

Dated: December 23, 2019